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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,541	11/20/2003	David A. Gough	041673-2114	3436
30542	7590	09/12/2006		
FOLEY & LARDNER LLP P.O. BOX 80278 SAN DIEGO, CA 92138-0278			EXAMINER NATNITHITHADHA, NAVIN	
			ART UNIT	PAPER NUMBER
			3735	

DATE MAILED: 09/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/719,541

Applicant(s)

GOUGH, DAVID A.

Examiner

Navin Natnithithadha

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 January 2004.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-28 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1-19 and 23-28 is/are rejected.  
7) ☒ Claim(s) 20-22 is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☒ The drawing(s) filed on 20 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 20040120.

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 1-19 and 23-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gough, U.S. Patent No. 4,650,547 A ("Gough"), as applied to claims above, and further in view of Cozzette et al, U.S. Patent No. 5,112,455 A ("Cozzette").

Claim 1: Gough discloses a measuring device for determining concentration of a first material (large molecule component) in an environment in contact with the device, which first material reacts within the device in presence of a catalyst with a second

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material (small molecule component) to form a third material (see column 5, line 58 to column 6, line 2); and which device comprises:

a membrane comprising a body (30), a surface (33) in contact with the environment and at least one discrete hydrophilic region (32) in communication with the body;

a catalyst (see column 6, lines 1-2);

at least one critical zone 36 within the hydrophilic region containing the catalyst (see column 6, lines 1-2); and

at least one sensor 10 (see fig. 1).

Gough does not expressly disclose a control responsive to the signal for comparing the signal to a reference to determine the concentration of the first material in the environment. However, it is a common procedure to compare the response of a sensor with a reference in a sample fluid and relating the signal measurements and then determining the concentration of an analyte species in the sample fluid based on the signal relationship. For example, Cozzette teaches such a procedure involving an external computational means connected to a sensor and a reference electrode.

Therefore, it would have been obvious for one of ordinary skill in the art at the time the invention was made to combine the teachings of Cozzette et al with the teachings of Gough in order to "...obtain conveniently precise, accurate determinations of the concentration of analyte of clinical interest" (see Cozzette et al, column 4, lines 47-56).

Claims 2-17, 23, and 25-27: As to claims 2-5, Gough discloses the environment is interstitial fluid or blood or encountered by an implanted sensor (see column 7, lines 14-

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19). As to claims 6, 8, and 10, Gough discloses the first material as generally a large molecule component, which would include glucose, lactate, and cholesterol compounds (see column 3, lines 32-34). As to claims 7, 9, and 11, Gough discloses the catalyst as an enzyme, which includes crosslinking oxidases (see column 5, lines 17-20, and column 6, lines 48-54). As to claim 12, Gough discloses the second material is oxygen (see column 3, lines 34-36). As to claim 13, Gough discloses the third material is hydrogen peroxide (see column 6, line 55). As to claim 14, Gough discloses the membrane body 30 consists of polydimethylsiloxane, polymers of tetrafluoroethylene or its fluoro-chloro analogues alone or as copolymers with ethylene or propylene, polyethylene, polypropylene, and other oxygen-imbibing polymeric materials (see column 5, lines 20-29). As to claim 15, Gough discloses the hydrophilic region 32 consist of polyacrylamide gel, glutaraldehyde-crosslinked collagen, polyhydroxyethylmethacrylate and its derivatives, and copolymers and other hydrophilic polymers (see column 5, lines 13-19). As to claim 16, Gough discloses the hydrophilic region 32 has essentially an identical surface area on the inner and outer faces of the membrane (see figure 4). As to claim 17, Gough discloses the hydrophilic region has a larger surface area on the inner face of the membrane as compared to the outer face of the membrane (see fig. 5). As to claims 23 and 27, Gough discloses the critical zone is coincident with the hydrophilic region (see fig. 4). As to claims 18 and 19, the Examiner has interpreted that the hydrophilic region 32 has separate regions (not labeled, see fig. 4) of variety of sizes and corresponds to a single sensor. As to claims 25 and 26, the

base of the hydrophilic region is nearly identical or larger in area to the area of its corresponding sensor (see figs 1 and 4).

Claims 24 and 28: Gough does not teach a single hydrophilic region corresponds to more than one sensor or a plurality of sensors, or a single hydrophilic region corresponds to a plurality of sensors. However, at the time the invention was made it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify Gough to have the above features because Applicant has not disclosed that the features provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the above features because Gough discloses that the invention relates to a membrane useful in electro-chemical sensor devices, which may have more than one sensor.

#### ***Allowable Subject Matter***

2. Claims 20-22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

3. The following is a statement of reasons for the indication of allowable subject matter:

As to claims 20 and 22, the prior art does not teach the subject matter of claim 1 including an average vector direction of diffusion of the first material in

the critical zone is substantially parallel to an average vector direction of diffusion of the first material in the hydrophilic region.

As to claim 21, the prior art does not teach the subject matter of claim 1 including a critical zone with an average equivalent radius and a length, wherein the average equivalent radius of the critical zone is less than the length of the critical zone, wherein the equivalent radius is obtained by dividing the cross-sectional area of the critical zone by  $\pi$  and then taking a square root of the resulting quantity.

### ***Conclusion***

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Navin Natnithithadha whose telephone number is (571) 272-4732. The examiner can normally be reached on Monday-Friday, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Navin Natnithithadha  
Patent Examiner - GAU 3735  
05 September 2006